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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,040	03/01/2002	Joseph C. Cauthen	08442.0002-04	8078

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EXAMINER	
CHATTOPADHYAY, URMI	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/085,040	CAUTHEN, JOSEPH C.	
	Examiner	Art Unit	
	Urmi Chattopadhyay	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49-62,65,66,70-85 and 92-101* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49-62,65,66,70-85 and 92-101* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

1. The request filed on 11/18/04 for a Request for Continued Examination (RCE) under 37 CFR 1.114 based on Application No. 10/085,040 is acceptable and a RCE has been established. An action on the RCE follows.

Response to Amendment

2. The amendment filed 10/12/04 has been entered. Claims 45-48, 64, 67-69 and 86-91 have been canceled, and new claims 94-101 have been added. All pending claims, which are claims 49-62, 65, 66, 70-85 and 92-101, are being considered for further examination on the merits.

Allowable Subject Matter

3. The previously indicated allowability of claims 64-66 is withdrawn in view of the reference(s) to Wardlaw (WO 99/02108 A1). Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 49-57, 60, 62, 65, 66, 70, 71, 75-80, 92 and 94-101 are rejected under 35 U.S.C. 102(a) as being anticipated by Wardlaw (WO 99/02108 A1, as cited in applicant's IDS).

Wardlaw discloses an implantable device with all the elements of claim 49. See Figs. 1A and 1B for a device (10) comprising a body (16) having a delivery configuration (Figs. 6A and 6B; valve 18 is open) and an implanted configuration (Fig. 8B; valve 18 is closed). The device (10) further comprises a flexible bladder (12). In the delivery configuration (when valve 18 is open), the device (10) has at least one dimension (deflated bladder 12) no larger than the aperture dimension (Figs. 6A and 6B), and in the implanted configuration (when valve 18 is closed), the device (10) has at least one second dimension (Fig. 8B) larger than the aperture dimension. Because the device (10) replaces the nucleus pulposis and spans the aperture in the annulus of a patient's intervertebral disc, it is capable of treating the annulus.

With respect to claim 50, the second dimension (height) lies along a different axis than the first dimension (width).

With respect to claims 51-53, the device (10) with the bladder (12) in its unexpanded delivery configuration or not fully expanded configuration is certainly *capable* of subannular reorientation comprising rotation (about its longitudinal axis) or deformation.

Claim 54, see Figs. 7A and 7B for the second dimension resulting from causing the device to expand from the delivery configuration. Also see page 17, lines 22-24.

Claims 55 and 56 do not further structurally limit the device. How and when the aperture dimension is measured does not affect the structure of the device.

Claim 57, see page 11, lines 18-20 for synthetic biocompatible material.

Claim 60, see page 11, line 20 for polytetrafluoroethylene (Gortex®).

Claim 62, see page 12, lines 15 and 24 for at least a portion of the device being formed at least in part of flexible, resilient material (mesh).

Claims 65, 66 and 94-96, see pages 3-4, lines 35-1 for the bladder further comprising a hydrogel in a liquid or powdered (dehydrated) state.

Claims 70 and 71, see page 3, line 19 and page 11, lines 18-20 polymeric sheet.

Claim 75, see page 12, lines 15-18 for porous mesh.

Claim 76, see page 5, lines 5 and 17 for fibrous material (Dacron® and carbon fibres).

Claim 77, see page 3, lines 19-20 for biocompatible fabric.

Claim 78, see page 11, lines 30-31 for the woven outer layer of bladder (12) providing as an attachment element because it facilitates fixation of the device (10) to anatomical features of the patient.

Claims 79 and 80 do not further structurally limit the device. The anatomical features to which the attachment element is fixating the device do not affect the structure of the device.

Claim 92, see page 5, line 5 for polymer fibers (Dacron®).

Claims 97 and 98, see page 11, lines 19-29 for a semi-permeable member (outer woven layer) and a layer that is non-permeable (inner layer) to all but water and very low molecular weight materials.

Claim 99, see page 17, lines 23-24 for the bladder (12) being inflatable.

Claim 100, see page 17, lines 22-24 for the bladder (12) being expandable by injection.

Claim 101, see Figs. 8A and 8B for the bladder (12) being configured to fill a void in the intervertebral disc cavity in an expanded state.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wardlaw in view of Ray et al. (USPN 4,904,260, as cited in applicant's IDS).

Wardlaw discloses an implantable device with all the elements of claim 49, but is silent to at least a portion of the device being formed at least in part of polyethylene terephalate, as required by claim 58. Ray et al. teaches an implantable prosthetic disc device wherein the device is made from, as an alternative to PTFE, a tightly woven fabric of oriented polyethylene terephalate fibers that has been plasma-deposited with polytetrafluoroethylene ("Plasma TFE") in order to provide a semi-permeable membrane with a pore size that is sufficiently small to block the passage human cells. See columns 4-5, lines 59-1. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Ray et al. to use, as an alternative to the PTFE (Gortex®) of Wardlaw, "Plasma TFE" because it is a suitable material for a prosthetic disc by being semi-permeable with a pore size sufficiently small to block the passage human cells.

8. Claims 59, 61, 72-74, 81-85 and 93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wardlaw in view of Bao et al. (USPN 6,224,630, as cited in applicant's IDS).

Wardlaw discloses an implantable device with all the elements of claim 49, but is silent to at least a portion of the device being formed at least in part of allograft, autograft and xenograft, as required by claims 72, 73 and 74, respectively. Bao et al. teaches a disc annulus aperture device wherein the device is embedded with autograft, allograft or xenograft (cell culture) in order to enhance tissue ingrowth. See column 4, lines 4-10 and column 9, lines 57-65. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Bao et al. to modify the device of Wardlaw by incorporating to the outer woven layer of bladder (12) living cells (autograft, allograft or xenograft) in order to enhance tissue ingrowth.

Wardlaw is also silent to at least a portion of the device being formed at least in part of material to facilitate regeneration of disc tissue, as required by claim 61, and wherein the material is a growth factor, as required by claim 93. Bao et al. teaches incorporating to the disc annulus aperture device growth factors in order to actively facilitate and stimulate tissue ingrowth. See column 9, lines 19-27. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Bao et al. to modify the device of Wardlaw by incorporating to the outer woven layer of bladder (12) growth factors in order to actively facilitate and stimulate tissue ingrowth.

Wardlaw is also silent to the device further comprising an attachment means for securing the device within the patient, wherein the attachment means comprise at least one suture, tension bands, staples, and barbs, as required by claims 81-85. Bao et al. teaches using the required attachment means, including bioresorbable sutures, in order to enhance short-term fixation of the device. See column 14, lines 12-23. It would have been obvious to one of ordinary skill in the

art at the time of applicant's invention to look to the teachings of Bao et al. to modify the device of Wardlaw by including the required attachment means, including bioresorbable sutures (claim 59), in order to enhance short-term fixation of the device (10), prior to tissue growing into the outer woven layer of the bladder (12) for long-term fixation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Urmi Chattopadhyay whose telephone number is (571) 272-4748. The examiner can normally be reached on Tuesday-Thursday 10:00am - 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Urmi Chattopadhyay
Art Unit 3738

David J. Isabella
Primary Examiner